Reference number(s)
1705-A

SPECIALTY GUIDELINE MANAGEMENT

TREANDA (bendamustine)
BENDEKA (bendamustine)
BELRAPZO (bendamustine)

POLICY

I. INDICATIONS

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

A. FDA-Approved Indications
1. Chronic lymphocytic leukemia (CLL)
2. Indolent B-cell non-Hodgkin lymphoma (NHL) that has progressed during or within six months of treatment with rituximab or a rituximab-containing regimen

B. Compendial Uses
1. Classical Hodgkin lymphoma (CHL)
2. Multiple myeloma (MM)
3. Non-Hodgkin lymphoma (NHL)
   i. Adult T-cell leukemia/lymphoma (ATLL)
   ii. Acquired immune deficiency syndrome (AIDS)-related B-cell lymphoma
   iii. CLL/small lymphocytic lymphoma (SLL)
   iv. Diffuse large B-cell lymphoma (DLBCL)
   v. Histologic transformation of marginal zone lymphoma to diffuse large B-cell lymphoma
   vi. Histologic transformation of follicular lymphoma to diffuse large B-cell lymphoma
   vii. High grade B-cell lymphoma
   viii. Follicular lymphoma
   ix. Marginal zone lymphoma
      a. Nodal marginal zone lymphoma
      b. Gastric mucosa associated lymphoid tissue (MALT) lymphoma
      c. Nongastric MALT lymphoma
      d. Splenic marginal zone lymphoma
   x. Mantle cell lymphoma (MCL)
   xi. Mycosis fungoides (MF)/Sezary syndrome (SS)
   xii. Peripheral T-cell lymphoma (PTCL)
   xiii. Primary cutaneous B-cell lymphoma
   xiv. Primary cutaneous CD30+ T-cell lymphoproliferative disorder: cutaneous anaplastic large cell lymphoma (ALCL)
   xv. Post-transplant lymphoproliferative disorders
   xvi. Hepatosplenic Gamma-Delta T-Cell lymphoma
4. Waldenström's macroglobulinemia/lymphoplasmacytic lymphoma
5. Small cell lung cancer

All other indications are considered experimental/investigational and are not a covered benefit.

II. CRITERIA FOR INITIAL APPROVAL

A. Non-Hodgkin lymphoma (NHL)

Authorization of 12 months may be granted for treatment of NHL with any of the following subtypes:

1. Follicular lymphoma
2. Chronic lymphocytic leukemia/small lymphocytic leukemia (CLL/SLL) without chromosome 17p deletion or TP53 mutation
3. High-grade B-cell lymphoma when both of following are met:
   a. The requested agent is used as second-line or subsequent therapy, and
   b. The patient is not a candidate for transplant.
4. Diffuse large B-cell lymphoma (DLBCL) when the both of the following are met:
   a. The requested agent is used as second-line or subsequent therapy, and
   b. The patient is not a candidate for transplant.
5. Histologic transformation of marginal zone lymphoma to diffuse large B-cell lymphoma when the patient has received at least two chemoimmunotherapy regimens.
6. Histologic transformation of follicular lymphoma to diffuse large B-cell lymphoma when the patient has received at least two chemoimmunotherapy regimens.
7. Adult T-cell leukemia/lymphoma (ATLL) when both of the following are met:
   a. The requested agent is used as a single agent, and
   b. The requested agent is used as second-line or subsequent therapy.
8. AIDS-related B-cell lymphoma when both of the following are met:
   a. The requested agent is used as second-line or subsequent therapy, and
   b. The patient is not a candidate for transplant.
9. Marginal zone lymphoma
   a. Nodal marginal zone lymphoma when used in combination with rituximab or obinutuzumab.
   b. Gastric MALT lymphoma when used in combination with rituximab or obinutuzumab.
   c. Nongastric MALT lymphoma when used in combination with rituximab or obinutuzumab.
   d. Splenic marginal zone lymphoma when used in combination with rituximab or obinutuzumab.
10. Mantle cell lymphoma (MCL) when either of the following are met:
    a. The requested agent is used as a single agent, or
    b. The requested agent is used in combination with rituximab.
11. Mycosis fungoides (MF)/Sezary syndrome (SS)
12. Peripheral T-cell lymphoma (PTCL) when both of the following are met:
    a. The requested agent is used as a single agent, and
    b. The requested agent is used as second-line or subsequent therapy.
13. Primary cutaneous B-cell lymphoma when both of the following are met:
    a. The requested agent is used as second-line or subsequent therapy.
    b. The patient is not a candidate for transplant.
14. Cutaneous anaplastic large cell lymphoma (ALCL) when both of the following are met:
    a. The requested agent is used as a single agent, and
    b. The requested agent is used for relapsed or refractory disease.
15. Post-transplant lymphoproliferative disorders when used as second-line or subsequent therapy.
16. Hepatosplenic gamma-delta T-Cell lymphoma when both of the following are met:
    a. The requested agent is used as a single agent, and
    b. The requested agent is used for refractory disease.

B. Waldenström's macroglobulinemia/lymphoplasmacytic lymphoma

Authorization of 12 months may be granted for treatment of Waldenström's macroglobulinemia/lymphoplasmacytic lymphoma when either of the following are met

1. The requested agent will be used in combination with rituximab, or

2. The requested agent will be used as a single agent.

C. Multiple myeloma (MM)

Authorization of 12 months may be granted for treatment of MM when both of the following criteria are met:

1. The disease is relapsed or progressive, and
2. The requested agent will be used in any of the following regimens:
   a. In combination with lenalidomide and dexamethasone, or
   b. In combination with bortezomib and dexamethasone, or
   c. As a single agent.

D. Classical Hodgkin lymphoma (CHL)

Authorization of 12 months may be granted for treatment of CHL when both of the following criteria are met:

1. The requested agent will be used as second line, subsequent therapy, or palliative therapy, and
2. The requested agent will be used in any of the following regimens:
   a. In combination with brentuximab vedotin, or
   b. In combination with gemcitabine and vinorelbine, or
   c. As a single agent.

E. Small cell lung cancer (SCLC)

Authorization of 12 months may be granted for treatment of SCLC when both of the following criteria are met:

1. The requested agent is being used for subsequent therapy, and
2. The requested agent will be used as a single agent.

III. CONTINUATION OF THERAPY

Authorization of 12 months may be granted for continued treatment in members requesting reauthorization for an indication listed in Section II who have not experienced disease progression or an unacceptable toxicity.

IV. REFERENCES

1. Treanda [package insert]. North Wales, PA: Teva Pharmaceuticals USA, Inc.; December 2017.
2. Bendeka [package insert]. North Wales, PA: Teva Pharmaceuticals USA, Inc.; September 2017.
3. Belrapzo [package insert]. Woodcliff, NJ; Eagle Pharmaceuticals, Inc; December 2018.
4. The NCCN Drugs & Biologics Compendium® © 2019 National Comprehensive Cancer Network, Inc. https://www.nccn.org. Accessed April 28, 2019.